# RUTH L. KIRSCHSTEIN NATIONAL RESEARCH SERVICE AWARDS FOR INDIVIDUAL POSTDOCTORAL FELLOWS (F32)

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This program announcement supersedes PA-00-104, which appeared in the NIH Guide on June 1, 2000.

## THIS PA CONTAINS THE FOLLOWING INFORMATION

- Purpose
- Mechanism of Support
- Eligibility Requirements
- Eligible Sponsoring Institutions
- Allowable Costs
- Supplementation of Stipends and Compensation
- Tax Liability
- Service Payback Requirements
- Leave Policies
- Part-Time Training
- Other Special Requirements
- Where to send Inquiries
- Submitting an Application
- Peer Review Process
- Review Criteria
- Award Criteria
- Required Federal Citations

#### **PURPOSE**

The Congress of the United States enacted the National Research Service Act (NRSA) Program in 1974 to help ensure that a diverse pool of highly trained scientists will be available in adequate numbers and in appropriate research areas to carry out the Nation's biomedical and behavioral research agenda. In 2002, the National Research Service Award Program was renamed the Ruth L. Kirschstein National Research Service Award Program as a tribute to Dr. Kirschstein's years of exceptional service to the Nation. Additional details related to this legislative change are available at <a href="http://grants.nih.gov/training/news.htm">http://grants.nih.gov/training/news.htm</a>. Under this congressional authority, the National Institutes of Health (NIH) awards individual postdoctoral fellowships (F32) to promising applicants with the potential to become productive, independent investigators in fields related to the mission of the NIH constituent institutes and centers.

#### MECHANISM OF SUPPORT

This program announcement for the individual Postdoctoral Fellowship Award (F32) is issued under the auspices of the Kirschstein-NRSA Act. The proposed postdoctoral training must be within the broad scope of biomedical, behavioral, or clinical research and must offer an opportunity to enhance the fellow's understanding of the health-related sciences and extend his/her potential for a productive research career.

Fellowship awardees are required to pursue their research training on a full-time basis, devoting at least 40 hours per week to the training program. Research clinicians must devote full-time to their proposed research training and must restrict clinical duties within their full-time research training experience to activities that are directly related to the research training experience. A Kirschstein-NRSA fellowship (F32) may not be used to support studies leading to the M.D., D.O., D.D.S., D.V.M., or other similar health-professional degrees. Neither may these awards be used to support the clinical years of residency training.

The Secretary, U.S. Department of Health and Human Services (DHHS), is required by law, to consider the Nation's overall needs for biomedical personnel and to give special consideration to physicians and other health professionals who agree to undertake a minimum of 2 years of biomedical, behavioral or clinical research. NIH recognizes the critical importance of training clinicians to become researchers and encourages them to apply. For those who have a health professional degree, the proposed training may be used to satisfy a portion of the degree requirements for a master's degree, a doctoral degree or any other advanced research degree program. Women, minorities, and individuals with disabilities are encouraged to apply.

# ELIGIBILITY REQUIREMENTS

Citizenship. By the time of award, candidates for the postdoctoral fellowship award must be citizens or non-citizen nationals of the United States, or must have been lawfully admitted to the United States for Permanent Residence (i.e., possess a currently valid Alien Registration Receipt Card I-551, or other legal verification of such status). Non-citizen nationals are generally persons born in outlying possessions of the United States (i.e., American Samoa and Swains Island). Individuals on temporary or student visas are not eligible. Individuals may apply for the F32 in advance of admission to the United States as a Permanent Resident recognizing that no award will be made until legal verification of Permanent Resident status is provided.

Degree Requirements. Before a Kirschstein-NRSA postdoctoral fellowship award can be activated, the individual must have received a Ph.D., M.D., D.O., D.C., D.D.S., D.V.M., O.D., D.P.M., Sc.D., Eng.D., Dr. P.H., D.N.S., N.D., Pharm.D., D.S.W., Psy.D., or equivalent doctoral degree from an accredited domestic or foreign institution. Certification by an authorized official of the degree-granting institution that all degree requirements have been met is also acceptable.

Duration of Support. Individuals may receive up to 3 years of aggregate Kirschstein-NRSA support at the postdoctoral level, including any combination of support from institutional training grants (T32) and individual fellowship awards (F32). Applicants must consider any prior Kirschstein-NRSA postdoctoral research training in determining the duration of fellowship support requested. Training beyond the 3-year aggregate limit may be possible under certain exceptional circumstances, but a waiver from the NIH awarding component is required. Individuals seeking additional Kirschstein-NRSA support beyond the third year are strongly advised to consult with relevant NIH staff before preparing a justification. Any waiver will require a detailed justification of the need for additional research training.

Sponsor. Before submitting a fellowship application, the applicant must identify a sponsoring institution and an individual who will serve as a sponsor (also called mentor or supervisor) and will supervise the training and research experience.

The applicant's sponsor should be an active investigator in the area of the proposed research who will directly supervise the candidate's research. The sponsor must document the availability of research support and facilities for high-quality research training. In most cases, the F32 supports research training experiences in new settings in order to maximize the acquisition of new skills and knowledge. However, in unusual circumstances, applicants may propose postdoctoral training experiences at their doctorate institution or at the institution where they have been training for more than a year. In such cases, the applicant must carefully document the opportunities for new research training experiences specifically designed to broaden their scientific background.

Foreign Sponsorship. Applicants requesting fellowship support for foreign research training must show in the application that the foreign institution and sponsor offer unique

opportunities and clear scientific advantages over positions currently available in the United States.

#### ELIGIBLE SPONSORING INSTITUTIONS

The sponsoring institution may be any of the following:

- For-profit or non-profit organizations
- Public or private institutions, such as universities, colleges, hospitals, and laboratories Units of State and local governments
- Eligible agencies and labs of the Federal government including NIH intramural labs
- Domestic or foreign

#### ALLOWABLE COSTS

Stipends. Kirschstein-NRSA awards provide stipends to postdoctoral fellows as a subsistence allowance to help defray living expenses during the research training experience. The awards are not provided as a condition of employment with either the Federal government or the sponsoring institution. The stipend level for the first year of Kirschstein-NRSA support is determined by the number of full years of relevant postdoctoral experience at the time the award is issued (not at the time of activation, see below). Fellows with less than one full year of postdoctoral experience at the time of award will receive initial support at the zero level. Relevant experience may include research (including research in industry), teaching, internship, residency, clinical duties, or other time spent in full-time studies in a health-related field beyond that of the qualifying doctoral degree. The stipend schedule is updated nearly every year and applicants are advised to check for the posting of the current stipend schedule on the NIH website at <a href="http://grants.nih.gov/training/nrsa.htm">http://grants.nih.gov/training/nrsa.htm</a>. The awarding NIH institute or center will adjust awards on the anniversary date of the fellowship award to ensure consistency with the stipend schedule in effect at that time.

The stipend for each subsequent year of Kirschstein-NRSA support is the next level of experience using the stipend schedule in effect at that time. Stipends will be adjusted on the anniversary date of the award and will not be changed mid-year to accommodate an increase in the level of experience. No departure from the published Kirschstein-NRSA stipend schedule may be negotiated between the institution and the fellow.

For fellows sponsored by domestic non-federal institutions, the stipend will be paid through the sponsoring institution. For fellows sponsored by Federal or foreign institutions, the monthly stipend payment will be deposited in the fellow's U.S. bank account or paid directly to the fellow by U.S. Department of Treasury check.

Tuition and Fees. The NIH will offset the combined cost of tuition and fees at the following rate: 100 percent of all costs up to \$3,000 and 60 percent of costs above \$3,000. Costs associated with tuition and fees are allowable only if they are required for specific courses in support of the research training experience supported by the fellowship. A full description of the tuition policy is contained within the NRSA section of the Grants Policy Statement at <a href="http://grants.nih.gov/grants/policy/policy.htm">http://grants.nih.gov/grants/policy/policy.htm</a>.

Institutional Allowance. At the time of publication, fellows receive an institutional allowance of \$5,500 per 12-month period to nonfederal, nonprofit, or foreign sponsoring institutions to help defray such awardee expenses as research supplies, equipment, health insurance (either self-only or family as appropriate), and travel to scientific meetings. Support for health insurance is allowable only if it is applied consistently for all individuals in a similar research training status regardless of the source of support. This allowance is intended to cover training related expenses for the individual awardee. The allowance is not available until the fellow officially activates the award. If an individual fellow is enrolled or engaged in training for less than 6 months of the award year, only one-half of that year's allowance may be charged to the grant. The Notice of Research Fellowship Award will be revised and the balance must be refunded to NIH.

NIH will provide an institutional allowance of up to \$4,400 for fellows sponsored by Federal laboratories or for-profit institutions for expenses associated with travel to scientific meetings, health insurance, and books. For fellows at for-profit institutions, the \$4,400 will be paid to the institution for disbursement to the fellow. Funds for fellows at Federal laboratories will be disbursed from the NIH awarding institute.

The Institutional Allowance is adjusted from time-to-time. Prospective applicants are advised to check for the current Institutional Allowance in the most recent documentation related to Kirschstein-NRSA stipends at <a href="http://grants.nih.gov/training/nrsa.htm">http://grants.nih.gov/training/nrsa.htm</a>.

Other Training Costs. Additional funds may be requested by the institution when the training of a fellow involves extraordinary costs for travel to field sites remote from the sponsoring institution; or, accommodations for fellows who are disabled, as defined by the Americans With Disabilities Act. The funds requested for costs of this nature must be reasonable in relationship to the total dollars awarded under the fellowship and must be directly related to the approved research training experience. Such additional funds shall be provided only in exceptional circumstances that are fully justified and explained by the sponsoring institution.

Awards for training at a foreign site may include a single economy or coach round-trip travel fare. No allowance is provided for dependents. U.S. flag air carriers must be used to the maximum extent possible when commercial air transportation is available for travel between the United States and a foreign country or between foreign countries. Funds are not provided to cover the cost of travel between the fellow's place of residence and a domestic training institution. However, in cases of extreme need or hardship, a one-way travel allowance may be authorized by the sponsoring institution. Such travel must be paid from the institutional allowance.

Facilities and Administrative Costs. F&A (indirect) costs are not allowed on individual fellowship awards.

# SUPPLEMENTATION OF STIPENDS, COMPENSATION, AND OTHER INCOME

The sponsoring institution is allowed to provide funds to the fellow in addition to the stipends paid by the NIH. Such additional amounts either may be in the form of augmented stipends (supplementation) or in the form of compensation, such as salary or tuition remission for services such as teaching or serving as a laboratory assistant, provided the conditions described below are met. Under no circumstances may the conditions of stipend supplementation or the services provided for compensation interfere with, detract from, or prolong the fellow's approved Kirschstein-NRSA training program.

Stipend Supplementation: Supplementation or additional support to offset the cost of living may be provided by the sponsoring institution. Supplementation does not require additional effort from the fellow. DHHS funds may not be used for supplementation under any circumstances. Additionally, no funds from other Federal agencies may be used for supplementation unless specifically authorized by the NIH and the other Federal Agency.

Compensation: The sponsoring institution may provide additional funds to a fellow in the form of compensation (as salary and/or tuition remission) for services such as teaching or serving as a research assistant. A fellow may receive compensation for services as a research assistant or in some other position on a Federal research grant, including a DHHS research grant. However, compensated services should occur on a limited, part-time basis apart from the normal research training activities, which require a minimum of 40 hours per week. In addition, compensation may not be paid from a research grant supporting the fellow's research training experience.

Educational Loans or G.I. Bill: An individual may make use of Federal educational loan funds and assistance under the Veterans Readjustment Benefits Act (G.I. Bill). Such funds are not considered supplementation or compensation. Postdoctoral fellows may also be eligible to participate in the NIH Extramural Loan Repayment Program. Information on this program is available at <a href="http://www.lrp.nih.gov/">http://www.lrp.nih.gov/</a>.

Concurrent Awards: A Kirschstein-NRSA fellowship may not be held concurrently with another federally sponsored fellowship or similar Federal award that provides a stipend or otherwise duplicates provisions of this award.

#### TAX LIABILITY

Section 117 of the Internal Revenue Code applies to the tax treatment of all scholarships and fellowships. Under that section, non-degree candidates are required to report as gross income any monies paid on their behalf for stipends, or any course tuition and fees required for attendance. Degree candidates may exclude from gross income (for tax purposes) any amount used for tuition and related expenses such as fees, books, supplies, and equipment required for courses of instruction at a qualified educational organization. The taxability of stipends, however, in no way alters the relationship between Kirschstein-NRSA trainees or fellows and their institutions.

Kirschstein-NRSA stipends are not considered salaries. In addition, trainees supported under the Kirschstein-NRSA are not considered to be in an employee-employer relationship with the NIH or the awardee institution. It is therefore, inappropriate and unallowable for institutions to charge costs associated with employment (such as FICA, workman's compensation, or unemployment insurance) to the fellowship award. It must be emphasized that the interpretation and implementation of the tax laws are the domain of the Internal Revenue Service (IRS) and the courts. The NIH takes no position on the status of a particular taxpayer, and it does not have the authority to dispense tax advice. Individuals should consult their local IRS office about the applicability of the law to their situation and for information on their tax obligations.

## SERVICE PAYBACK

As required by the NIH Revitalization Act of 1993, postdoctoral fellows incur a service obligation of 1 month for each month of support during the first 12 months of the Kirschstein-NRSA postdoctoral support. The 13th and subsequent months of Kirschstein-NRSA support are acceptable postdoctoral payback service. Thus, individuals who continue under the award for 2 years will have paid off their first year obligation by the end of the second year.

Applicants accepting an award for the first 12 months of Kirschstein-NRSA postdoctoral support must sign a payback agreement (PHS Form 6031) in which they agree to engage in health-related research training, research, and/or teaching for 12 months.

Those who do not pay back their obligation through continued Kirschstein-NRSA supported training may satisfy their obligation by serving in a position in which health-related research, research training, or teaching are the primary activities. Such individuals must engage in research, research training, or teaching at a rate of 20 or more hours per week averaged over a full work-year. Payback service may be conducted in an academic, governmental, commercial, or nonacademic environment, in the United States or in a foreign country. Examples of acceptable payback service include research associateships/assistantships, postdoctoral research fellowships, and college or high school science teaching positions. Examples of unacceptable payback service include clinical practice and administrative responsibilities not directly related to scientific research.

Payback service positions are arranged by the individual, not by the NIH. The NIH will review and approve the activity at the end of the year in which it occurs. Service to satisfy any outstanding obligation must be initiated within 2 years after termination of Kirschstein-NRSA support, and must be performed on a continuous basis. For individuals who fail to fulfill their service obligation, the United States is entitled to recover the total amount of Kirschstein-NRSA funds paid to the individual for the obligated period plus interest at a rate determined by the Secretary of the U.S. Department of Treasury. Financial payback must be completed within 3 years, beginning on the date the United States becomes entitled to recover such amount.

Under certain conditions, the Secretary, DHHS, may extend the period for starting service, permit breaks in service, extend the period of repayment, or otherwise waive the payback obligation when compliance would constitute a substantial hardship against equity and good conscience. Policies regarding the Kirschstein-NRSA payback obligation are explained in the Kirschstein-NRSA Section of the NIH Grants Policy Statement available at <a href="http://grants.nih.gov/grants/policy/policy.htm">http://grants.nih.gov/grants.nih.gov/grants/policy/policy.htm</a>. Specific questions may appear in a list of Frequently Asked Questions that appears on the Web at <a href="http://grants.nih.gov/training/faq\_fellowships.htm">http://grants.nih.gov/training/faq\_fellowships.htm</a>. Other questions on payback should be directed to the appropriate NIH institute contact.

## LEAVE POLICIES

In general, fellows may receive stipends during the normal periods of vacation and holidays observed by individuals in comparable training positions at the sponsoring institution. For the purpose of these awards, however, the period between the spring and fall semesters is considered to be an active time of research and research training and is not considered to be a vacation or holiday. Fellows may receive stipends for up to 15 calendar days of sick leave per year. Sick leave may be used for the medical conditions related to pregnancy and childbirth. Fellows may also receive stipends for up to 30 calendar days of parental leave per year for the adoption or the birth of a child when those in comparable training positions at the grantee institution have access to paid leave for this purpose and the use of parental leave is approved by the program director.

A period of terminal leave is not permitted and payment may not be made from fellowship funds for leave not taken. Fellows requiring periods of time away from their research training experience longer than specified here must seek approval from the NIH awarding component for an unpaid leave of absence.

#### PART-TIME TRAINING

Under unusual and pressing personal circumstances, a fellow may submit a written request to the awarding component to permit less than full-time training. Such requests will be considered on a case-by-case basis. They must be approved by the awarding NIH Institute or Center in advance for each budget period. The nature of the circumstances

requiring the part-time training might include medical conditions, disability, or pressing personal or family situations such as child or elder care. Permission for part-time training will not be approved to accommodate other sources of funding, job opportunities, clinical practice, clinical training, or for other responsibilities associated with the fellow's position at the institution. In each case, the fellow must submit a written request countersigned by the sponsor and an appropriate institutional business official that includes documentation supporting the need for part-time training. The written request also must include an estimate of the expected duration of the period of part-time training, an assurance that the fellow intends to return to full-time training when that becomes possible, and an assurance that the trainee intends to complete the proposed research training program. In no case will it be permissible for the fellow to be engaged in Kirschstein-NRSA supported research training for less than 50 percent effort. Individuals who must reduce their commitment to less than 50 percent effort must take a leave-of-absence from Kirschstein-NRSA fellowship support. The fellowship notice of award will be reissued and the stipend will be pro-rated during the period of any approved part-time training. Part-time training may affect the rate of accrual or repayment of the service obligation for postdoctoral fellows.

# OTHER SPECIAL REQUIREMENTS

Fellowships must be administered in accordance with the current NRSA section of the Grants Policy Statement at <a href="http://grants.nih.gov/grants/policy/policy.htm">http://grants.nih.gov/grants/policy/policy.htm</a>), and any terms and conditions specified on the award notice.

Certification and Reporting Procedures. No application will be accepted without the applicant signing the certification block on the face page of the application. Individuals admitted to the United States as Permanent Residents must submit notarized evidence of legal admission prior to the award. A Payback Agreement Form (PHS 6031) must accompany the Activation Notice for any award that occurs during the individual's initial 12 months of Kirschstein-NRSA postdoctoral support. When support ends, the fellow must submit a Termination Notice (PHS 416-7) to the NIH. If the fellow has a payback obligation, he or she must notify the NIH of any change in address and submit Annual Payback Activities Certification Forms (PHS 6031-1) until the payback service obligation is satisfied. Forms will be provided to awardees by the NIH awarding component. Forms may also be found on the NIH Website at <a href="http://grants.nih.gov/grants/forms.htm">http://grants.nih.gov/grants/forms.htm</a>.

Inventions and Publications. Fellowships made primarily for educational purposes are exempted from the PHS invention requirements. F32 awards will not contain any provision giving PHS rights to inventions made by the awardee.

Data Sharing. It is the policy of the DHHS that the results and accomplishments of all funded activities should be made available to the public. This policy also applies to individuals supported by individual Kirschstein-NRSA postdoctoral fellowships. The sponsoring institution should place no restrictions on the publication of results in a timely manner.

Copyrights. Except as otherwise provided in the terms and conditions of the award, the recipient is free to arrange for copyright without approval when publications, data, or other copyrightable works are developed in the course of work under a PHS grant-supported project or activity. Any such copyrighted or copyrightable works shall be subject to a royalty-free, nonexclusive, and irrevocable license to the Government to reproduce, publish, or otherwise use them, and to authorize others to do so for Federal Government purposes.

## WHERE TO SEND INQUIRIES

As indicated above, applicants are strongly encouraged to contact the individuals designated below, in advance of preparing an application, for additional information concerning the areas of research, receipt dates, and other types of pre-application instructions.

National Institute on Aging (NIA)

Robin Barr, Ph.D.

Telephone: 301-496-9322 Email: mailto:rb42h@nih.gov

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Tina Vanderveen, Ph.D.

Office of Collaborative Research

Telephone: 301-443-2531 E-mail: mailto:tv9f@nih.gov

National Institute of Allergy and Infectious Diseases (NIAID)

Milton Hernandez, Ph.D. Telephone: 301-496-3775 Email: mailto:mh35c@nih.gov

National Institute of Arthritis and Musculoskeletal and Skin Diseases

(NIAMS)

Richard Lymn, Ph.D. Telephone: 301-594-5128 Email: mailto:rl28b@nih.gov

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

Richard Swaja, Ph.D. Telephone: 301-451-6771

E-mail: mailto:swajar@nibib.nih.gov

National Cancer Institute (NCI)

Lester Gorelic, Ph.D. and Cynthia Pond, Ph.D.

Telephone: 301-496-8580

Email: mailto:lg2h@nih.gov and cp32z@nih.gov

National Institute of Child Health and Human Development (NICHD)

Steven Klein, Ph.D. Telephone: 301-496-5541 Email: mailto:sk56d@nih.gov

National Institute on Deafness and Other Communication Disorders

(NIDCD)

Daniel Sklare, Ph.D. Telephone: 301-496-1804 Email: mailto:ds104i@nih.gov

National Institute of Dental and Craniofacial Research (NIDCR)

James Lipton, Ph.D. Telephone: 301-594-2618 Email: mailto:jl46d@nih.gov

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Division of Diabetes, Endocrinology, and Metabolic Diseases

James Hyde, Ph.D.

Telephone: 301- 594-7692 Email: mailto:jh486z@nih.gov

Division of Digestive Diseases and Nutrition

Judith Podskalny, Ph.D. Telephone: 301-594-8876 Email: mailto:jp53s@nih.gov

Division of Kidney, Urologic, and Hematologic Diseases

Terry Rogers Bishop, Ph.D. Telephone: 301-594-7717 Email: mailto:tb232j@nih.gov

National Institute on Drug Abuse (NIDA) Office of Science Policy and Communications Lucinda L. Miner, Ph.D.

Telephone: (301) 443-6071

Email: mailto:CM171W@NIH.GOV

Center on AIDS and Other Medical Consequences of Drug Abuse

Helen Cesari, M.Sc. Telephone: 301-402-1918 Email: mailto:hc30x@nih.gov

Division of Neuroscience and Behavioral Research

Charles Sharp, Ph.D. Telephone: 301-443-1887

Email: mailto:cs107m@nih.gov

Division of Epidemiology, Services and Prevention Research

Kathy Etz, Ph.D.

Telephone: 301-443-1514887 Email: mailto:ke25p@nih.gov

Division of Treatment Research and Development

Jamie Biswas, Ph.D. Telephone: 301-443-5280 Email: mailto:jb168r@nih.gov

National Institute of Environmental Health Sciences (NIEHS)

Carol Shreffler, Ph.D. Telephone: 919 - 541- 1445

Email: mailto:shreffl1@niehs.nih.gov

National Eye Institute (NEI)

Chyren Hunter, Ph.D. Telephone: 301-496-2020

Email: <a href="mailto:CLH@nei.nih.gov">mailto:CLH@nei.nih.gov</a> http://www.nei.nih.gov/funding/t32.htm

National Institute of General Medical Sciences (NIGMS)

John Norvell, Ph.D. Telephone: 301-594-0533

Email: mailto:norvellj@nigms.nih.gov

National Heart, Lung, and Blood Institute (NHLBI)

Sandra Colombini Hatch, M.D. Telephone: 301-435-0220

Email: mailto:hatchs@nhlbi.nih.gov

National Human Genome Research Institute (NHGRI)

Bettie J. Graham, Ph.D. Telephone: 301-496-7531 Email: mailto:bg30t@nih.gov National Institute of Mental Health (NIMH)

Mark Chavez, Ph.D.

Division of Mental Disorders, Behavioral Research, and AIDS

Telephone: 301-443-8942

Email: mailto:mchavez1@mail.nih.gov

Walter L. Goldschmidts, Ph.D.

Division of Neuroscience and Basic Behavioral Science

Telephone: (301) 443-3563

Email: mailto:wgoldsch@mail.nih.gov

Enid Light, Ph.D.

Division of Services and Intervention Research

Telephone: (301) 443-1185

Email: mailto:elight@mail.nih.gov

National Institute of Neurological Disorders and Stroke (NINDS)

Henry Khachaturian, Ph.D. Telephone: 301-496-4188 Email: mailto:hk11b@nih.gov

National Institute of Nursing Research (NINR)

Nell Armstrong, Ph.D., R.N. Telephone: (301) 594-5973

Email: mailto:armstrongn@nih.gov

National Center for Complementary and Alternative Medicine (NCCAM)

Nancy J. Pearson, Ph.D. Telephone: 301-594-0519

Email: mailto:pearsonn@mail.nih.gov

National Center for Research Resources (NCRR)

Franziska Grieder, D.V.M., Ph.D.

Telephone: 301-435-0744

Email: mailto:griederf@ncrr.nih.gov

NIH Office of Dietary Supplements (ODS)

Mary Frances Picciano, Ph.D. Telephone: 301-435-2920

Email: mailto:piccianom@od.nih.gov

If you are not sure whom to contact about this program, please call:

Walter T. Schaffer, Ph.D. Research Training Officer National Institutes of Health 6705 Rockledge Drive, Room 3537 Bethesda, Maryland 20892-7963

Phone: 301-435-2687 FAX: 301-480-0146

Email: mailto:ws11q@nih.gov

## SUBMITTING AN APPLICATION

Individuals must submit the application using the Ruth L. Kirschstein National Research Service Award Individual Fellowship Form (PHS 416-1, rev. 06/02) available at <a href="http://grants.nih.gov/grants/forms.htm">http://grants.nih.gov/grants/forms.htm</a>

APPLICATIONS MUST INCLUDE AT LEAST THREE SEALED LETTERS OF REFERENCE

APPLICATIONS WITHOUT AT LEAST THREE LETTERS OF REFERENCE MAY BE RETURNED OR DELAYED IN REVIEW.

If the applicant has been lawfully admitted to the United States for permanent residence, the appropriate item should be checked on the Face Page of the application. Applicants who have applied for and have not yet been granted admission as a permanent resident should check the Permanent Resident block on the Face Page of the PHS 416-1 application, and also write in the word "pending." A notarized statement documenting legal admission for permanent residence must be submitted prior to the issuance of an award.

If the fellowship application is submitted in response to a Program Announcement (PA) or Request for Application (RFA) from a particular NIH institute, the applicant should identify the number of the PA or RFA in Item 3.

Instructions in the Responsible Conduct of Research.

Applications must include the candidate's plans for obtaining instruction in the responsible conduct of research, including the rationale, subject matter, appropriateness, format, frequency and duration of instruction. The amount and nature of faculty participation must be described. No award will be made if an application lacks this component.

# Application Materials.

Applications must be prepared using the PHS 416-1 application form and instructions for Individual National Research Service Award Fellowships (rev. 06/02). The PHS 416-1 is available at <a href="http://grants.nih.gov/grants/forms.htm">http://grants.nih.gov/grants/forms.htm</a> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: <a href="mailto:GrantsInfo@nih.gov">mailto:GrantsInfo@nih.gov</a>.

APPLICATION PROCESSING: Applications must be mailed on or before the receipt dates for individual NRSA Fellowships described at <a href="http://grants.nih.gov/grants/funding/submissionschedule.htm">http://grants.nih.gov/grants/funding/submissionschedule.htm</a>. The Center for Scientific Review (CSR) will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an application already reviewed, but such application must include an Introduction addressing the previous critique.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within 8 weeks. Normally the complete review process takes between 5 and 8 months.

## INCOMPLETE APPLICATIONS WILL NOT BE REVIEWED

Submit a signed, typewritten original of the application (including the Checklist, Personal Data form, AT LEAST THREE SEALED REFERENCE LETTERS, and all other required materials) and two (2) exact, clear, single-sided photocopies of the signed application, in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

All applications submitted to the Center for Scientific Review must come via United States Postal Service or a recognized delivery/courier service. Individuals may not personally deliver packages to the building on Rockledge Drive. For further information please see <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-012.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-012.html</a>.

#### PEER REVIEW PROCESS

Complete applications will be assigned to the appropriate participating Institute and a suitable Scientific Review Group (SRG) in the Center for Scientific Review (CSR) or in the assigned NIH Institute or Center. Applicants will be notified by mail of their application's Institute and SRG assignment.

Applications receive two sequential levels of review. The first level is an assessment of the merit of the research training by an SRG, composed primarily of non-government scientists selected for their competence in research and research training in a scientific area related to the application. After the SRG meeting, the Scientific Review Administrator (SRA), a designated Federal official, who coordinates the review of applications for the SRG, prepares a written summary of the review of each application and forwards it to the appropriate NIH Institute. Staff within the assigned funding Institute or Center provides a second level of review.

#### REVIEW CRITERIA

The review criteria focus on four main components:

- Candidate: An assessment of the candidate's previous academic and research performance and the potential to become an important contributor to biomedical, behavioral, or clinical science.
- Sponsor and Training Environment: An assessment of the quality of the training environment and the qualifications of the sponsor as a mentor for the proposed research training experience.
- Research Proposal: The merit of the scientific proposal and its relationship to the candidate's career plans.
- Training Potential: An assessment of the value of the proposed fellowship experience as it relates to the candidate's needs in preparation for a career as an independent researcher.

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, the following items may be considered in the determination of scientific merit and the priority score:

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. (See criteria included in the section on Federal Citations, below).

INCLUSION OF WOMEN, MINORITIES AND CHILDREN IN RESEARCH: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and

subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria in the sections on Federal Citations, below).

CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH: If vertebrate animals are to be used in the project, the five items described on page 21 of the PHS 416-1 fellowship application instructions (rev. 6/2002) will be assessed (see <a href="http://grants.nih.gov/grants/forms.htm">http://grants.nih.gov/grants/forms.htm</a>).

Notification. Shortly after the SRG meeting, applicants will be notified by mail of the SRG recommendation and the name and phone number of the Institute program official responsible for the application. When the program official representing the Institute receives the written summary of the review, prepared by the SRA after the review meeting, a copy will be forwarded to the applicant.

Following the second-level review, the program official will notify applicants within the funding range of the final disposition of the application. Any questions on SRG recommendations and funding possibilities should be directed to the appropriate Institute program official, not the Scientific Review Administrator of the SRG.

## AWARD CRITERIA

NIH staff use the following criteria in making awards: (1) eligibility of the applicant; (2) the SRG recommendation of the overall merit of the application; (3) the relevance of the application to the Institute's research training priorities and program balance; and (4) the availability of funds.

Activation. No funds may be disbursed until the fellow has started training under the award and an Activation Notice (PHS 416-5) and (when appropriate) a Payback Agreement (PHS 6031) has been submitted to the NIH. An awardee has up to 6 months from the issue date on the award notice to activate the award. Under unusual circumstances, an NIH institute may grant an extension of the activation period upon receipt of a specific request from the fellow.

## REQUIRED FEDERAL CITATIONS

HUMAN SUBJECTS PROTECTION: Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

MONITORING PLAN AND DATA SAFETY AND MONITORING BOARD: Research components involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data

and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: <a href="http://grants.nih.gov/grants/guide/notice-files/not98-084.html">http://grants.nih.gov/grants/guide/notice-files/not98-084.html</a>).

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (<a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html</a>); a complete copy of the updated Guidelines are available at

http://grants.nih.gov/grants/funding/women min/guidelines amended 10 2001.htm
The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS: The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at

http://grants.nih.gov/grants/funding/children/children.htm

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# REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS:

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html</a>.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at <a href="http://grants.nih.gov/grants/stem\_cells.htm">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.htm</a> and at <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.htm">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.htm</a>.

Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see <a href="http://escr.nih.gov/">http://escr.nih.gov/</a>). It is the responsibility of the applicant to provide the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this

# PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT:

information will be returned without review.

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at <a href="http://grants.nih.gov/grants/policy/a110/a110">http://grants.nih.gov/grants/policy/a110/a110</a> guidance dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-

led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

#### **AUTHORITY AND REGULATIONS**

Kirschstein-NRSA awards are made under the authority of Section 487 of the Public Health Service Act as amended (42 USC 288), and Title 42 of the Code of Federal Regulations, Part 66. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at <a href="http://grants.nih.gov/grants/policy/policy.htm">http://grants.nih.gov/grants/policy/policy.htm</a>. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.